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10/595,371	02/16/2007	Duncan Keeble	78104107/N18438	8373

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EXAMINER

TANNER, JOCELIN C

ART UNIT

PAPER NUMBER

3731

NOTIFICATION DATE

DELIVERY MODE

04/23/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/595,371	Applicant(s) KEEBLE ET AL.	
	Examiner JOCELIN C. TANNER	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/13/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-13,15-19 and 22-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-13,15-19 and 22-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/13/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed 13 October 2008.

Claims 1, 5-13, 15-19 and 22-31 are now pending. The Examiner acknowledges the amendments to claims 1, 19 and 24, the cancellation of claims 2-4, 20 and 21, and The addition claims 27-31.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. **Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Geitz (US Patent No. 6,146,389).**

3. Regarding claim 15, Geitz teaches a stent deployment device having a stent, a “vascular graft”, or a “medical implant” (22) circumferentially compressed over the protective cap (20) at the distal end of a flexible endoscope or “articulated device” (10) (column 3, lines 12-15, line 37 and 44-45). Please see figure 1.

4. **Claims 16-19, 26, 29 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Danitz et al. (US PGPub No. 2004/0236316A1).**

5. Regarding claim **16**, Danitz et al. discloses a device including a plurality of detachable, hingeably connected segments attached by corresponding ends whereby a medical implant attached to an end of the device can be advanced through a catheter by pushing the other end of the device ([0030], Figs. 3a-3c, 10, 11). Danitz et al. discloses a catheter having an interior passage wherein multiple segments are arrayed within, each segment pivotally abuts adjacent segments and may adopt a curved path within the catheter, the segments are translatable within the passage, whereby the segment at one end of the line can:

- (i) can have a medical implant situated thereon, and
- (ii) can be advanced through at least a major portion of the length of the catheter interior passage to eject the medical implant from a passage exit [0060].

Examiner notes that the device of Danitz et al. is capable of having a medical implant mounted thereon to be advanced through a catheter. Regarding the limitation, "whereby a medical implant mounted at one end of the device can be advanced through a catheter by pushing on the other end of the device, the hinged connections allowing the device to follow a curved path through the catheter, characterized in that each segment is detachable from its adjacent segment(s)", the Examiner notes that the manner or method in which an device is to be utilized is not germane to the issue of patentability of the device itself (In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967)).

6. Regarding claims **17 and 19**, Danitz et al. discloses a segment having an internal passage spaced from the segment's outer circumference (Fig. 3A).

7. Regarding claims **18 and 31**, Danitz et al. discloses a channel defined on an outer surface or outer circumference of the socket wall that are aligned along a common path ([0020], Fig. 3A, 5A).

8. Regarding claim **26**, Danitz et al. discloses segments having diameters ranging from 0.5mm to 15mm which is within the claimed range of 10mm or less [0034].

9. Regarding claim **29**, Danitz et al. discloses a catheter that is partially spaced from the outer surfaces wherein the segments may be threaded within the passage [0060].

10. **Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Greenwood, Sr. et al. (US Patent No. 5,769,681).**

11. Regarding claim **1**, Greenwood, Sr. et al. discloses a device including a plurality of detachable, hingeably connected segments attached by corresponding ends whereby a medical implant attached to an end of the device can be advanced through a catheter by pushing the other end of the device. Greenwood, Sr. et al. discloses segments bearing a male part including a ball (632) and a pair of projections (632A) and a female

part including a socket (623) and slots (623B) wherein the male part engages with the female part of an adjacent segment (column 4, lines 30-40, Figs. 13, 14).

Examiner notes that the device of Poll is capable of having a medical implant mounted thereon to be advanced through a catheter. Regarding the limitation, "whereby a medical implant mounted at one end of the device can be advanced through a catheter by pushing on the other end of the device, the hinged connections allowing the device to follow a curved path through the catheter, characterized in that each segment is detachable from its adjacent segment(s)", the Examiner notes that the manner or method in which an device is to be utilized is not germane to the issue of patentability of the device itself (In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967)).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 1, 5-10, 22-25, 27, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danitz et al. (US PGPub No. 2004/0236316A1) in view of Van Hoose (US Patent No. 4,114,401).**

3. Regarding claim 1, Danitz et al. discloses a device including a plurality of detachable, hingeably connected segments attached by corresponding ends whereby a

medical implant attached to an end of the device can be advanced through a catheter by pushing the other end of the device ([0030], Figs. 3a-3c, 10, 11). However, Danitz et al. fails to disclose segments bearing a male part including a ball and a pair of projections and a female part including a socket and slots wherein the male part engages with the female part of an adjacent segment.

Examiner notes that the device of Danitz et al. is capable of having a medical implant mounted thereon to be advanced through a catheter. Regarding the limitation, "whereby a medical implant mounted at one end of the device can be advanced through a catheter by pushing on the other end of the device, the hinged connections allowing the device to follow a curved path through the catheter, characterized in that each segment is detachable from its adjacent segment(s)", the Examiner notes that the manner or method in which an device is to be utilized is not germane to the issue of patentability of the device itself (In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967)).

Van Hoose teaches a universal joint including a spherical ball (114) having a bore wherein a drive pin (128) is disposed to produce two projections (132, 134) from the ball which is slidably disposed within a socket (12) and slots (118, 120) that receive the projections of the ball (column 3, lines 34-51).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the joint of Danitz et al. with the universal joint of Van Hoose, to provide multiple degrees of freedom.

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4. Regarding claim **5**, the combination of Danitz et al. and Van Hoose discloses the claimed invention except for segments formed from a material sufficiently stiff to allow a moment of at least 1 Newton metre to be transmitted through the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have formed the segments from a material sufficiently stiff to allow a moment of at least 1 Newton metre to be transmitted through the device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

5. Regarding claim **6**, Danitz et al. discloses a device having 15 segments (Fig. 1F) or any number of links and link pairs dependent on the body region of use and desired length of the articulating mechanism [0048].

6. Regarding claims **7**, Danitz et al. discloses a segment having an internal passage that would allow a guide wire to pass therethrough ([0035, 0036], Fig. 3A).

7. Regarding claim **8**, Danitz et al. discloses a channel defined on an outer surface of the socket wall that are aligned along a common path ([0020], Fig. 5A).

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8. Regarding claim **9**, the combination of Danitz et al. and Van Hoose discloses the claimed invention except for a 1:1 to 1:5 ratio of the length to the widest diameter of each segment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the segments having a 1:1 to 1:5 ratio of the length to the widest diameter of each segment, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

9. Regarding claim **10**, the combination of Danitz et al. and Van Hoose discloses the claimed invention except for a maximum of 15 degrees of articulation between the longitudinal axes of two adjacent segments. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a maximum of 15 degrees of articulation between the longitudinal axes of two adjacent segments, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

10. Regarding claim **22**, Van Hoose teaches segments that snap-fit to an adjacent segment (column 3, lines 44-47, Figs. 5, 6).

11. Regarding claim **23**, Van Hoose teaches segments having projections (132, 134) engaged to adjacent segments (Fig. 6).

12. Regarding claim **24**, Van Hoose teaches projections (132, 134) that extend from the ball (114) (Figs. 5, 6).

13. Regarding claim **25**, the combination of Danitz et al. and Van Hoose discloses the claimed invention except for segments having lengths that are less than or equal to their diameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the segments having lengths that are less than or equal to their diameters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

14. Regarding claim **27**, Van Hoose teaches projections (132, 134) that protrude from the ball (114) and slots (118, 120) that extend along a wall of the socket (112) (column 3, lines 33-51, Figs. 5, 6).

15. Regarding claim **28**, Van Hoose teaches slots (118, 120) that are aligned along the same plane of the projections (132, 134) (column 3, lines 33-51, Figs. 5, 6).

16. Regarding claim **30**, Van Hoose teaches projections (132, 134) that protrude from a ball (114), a socket (112) bounded by a wall having slots (118, 120) that extend along a wall of the socket (112) wherein the ball is received within the socket of an

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adjacent segment and the projections are received within the slots (column 3, lines 33-51, Figs. 5, 6).

17. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danitz et al. (US PGPub No. 2004/0236316A1) in view of Van Hoose (US Patent No. 4,114,401), as applied to claim 1 above, and further in view of Geitz (US Patent No. 6,146,389).

Regarding claim **11 and 12**, the combination of Danitz et al. and Van Hoose discloses all of the limitations previously discussed except for a medical implant mounted on one end of the device.

Geitz teaches a stent deployment device having a stent, a “vascular graft”, or a “medical implant” (22) circumferentially compressed over the protective cap (20) at the distal end of a flexible endoscope or “articulated device” (10) (column 3, lines 12-15, line 37 and 44-45). Please see figure 1.

Because the combination of Danitz et al. and Van Hoose and Geitz teach known elements, i.e. endoscopes, it would have been obvious to one of ordinary skill in the art to have applied the known technique of attaching an implant to the distal end of the device of the combination of Danitz et al. and Van Hoose, as taught by Geitz, for the predictable result of increasing the flexibility and maneuverability for positioning a stent within a vessel.

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18. Regarding claim **13**, Danitz et al. discloses a catheter having an interior passage wherein multiple segments are arrayed within [0060].

12. **Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greenwood, Sr. et al. (US Patent No. 5,769,681).**

Regarding claim **5**, Greenwood, Sr. et al. discloses the claimed invention except for segments formed from a material sufficiently stiff to allow a moment of at least 1 Newton metre to be transmitted through the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have formed the segments from a material sufficiently stiff to allow a moment of at least 1 Newton metre to be transmitted through the device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

19. Applicant's arguments with respect to claims 1, 5-13, 15-19 and 22-31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Poll (US Patent No. 5,343,718), Calverley (US Patent No.

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2,662,335) and Belson et al. (US Patent No. 6,610,007) are related to articulating segments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)? If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
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Examiner, Art Unit 3731

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